14° Meeting di Aggiornamento Acne e Dermatosi Correlate
ACNE FERRARA (AC FE)
24-25 Novembre 2017

I Topici per l'Acne nel 2018: Nuovi Orizzonti

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(Direttore Prof.ssa M.Corazza)

ClinicalTrials.gov > Acne > Topical therapy

145 studies found

- already known products (procedures included):

96

- new products (minocycline, lumeteporfin, omiganan, repicel, cortexolone, ……)

49

Expert Opin Investig Drugs. 2017 Jul;26(7):813-823. doi: 10.1080/13543784.2017.1337745. Epub 2017 Jun 19.

Anti-acne drugs in phase 1 and 2 clinical trials.

Zouboulis CC[1], Dessinioti C[2], Tsatsou F[1], Gollnick HPM[3].

INTRODUCTION:

Despite the impressive increase of knowledge on acne etiology accumulated during the last 20 years, few efforts have been overtaken to introduce new therapeutic regiments targeting the ideal treatment of acne. The increasing emergence of microbial resistance associated with antibiotics, teratogenicity, particularly associated with systemic isotretinoin, and the need for an adverse drug profile, which can be tolerated by the patient, make the need of new pathogenesis relevant anti-acne agents an emerging issue. Areas covered: A search for phase 1 and 2 acne treatment trials in the US National Institutes of Health database of clinical trials and the European Medicines Agency database with the key words 'acne' and 'treatment' was carried out, on 6 January 2017. Expert opinion: The detected trials mostly investigate topical agents that may act via sebosuppressive effects, antimicrobial properties or anti-inflammatory actions. The compounds under investigation include olumacostat glasaretil, cortexolone 17α-propionate, stearoyl-CoA desaturase 1 inhibitors, agents affecting the melanocortin system, omiganan, and minocycline. Systemic studied anti-acne drugs include finasteride, biologics, low dose anti-inflammatory antibiotics, and leukotriene B4 inhibitors.

KEYWORDS:

Acne; drug development; investigational drugs; phase 1; phase 2

PMID: 28627277 DOI: 10.1080/13543784.2017.1337745

J Invest Dermatol. 2017 Jul;137(7):1415-1423. doi: 10.1016/j.jid.2016.12.031. Epub 2017 Mar 1.

Inhibition of Sebum Production with the Acetyl Coenzyme A Carboxylase Inhibitor Olumacostat Glasaretil.

Hunt DW[1], Winters GC[2], Brownsey RW[3], Kulpa JE[3], Gilliland KL[4], Thiboutot DM[4], Hofland HE[5].

Olumacostat glasaretil (OG) is a small molecule inhibitor of acetyl coenzyme A (CoA) carboxylase (ACC), the enzyme that controls the first rate-limiting step in fatty acid biosynthesis. Inhibition of ACC activity in the sebaceous glands is designed to substantially affect sebum production, because over 80% of human sebum components contain fatty acids. OG inhibits de novo lipid synthesis in primary and transformed human sebocytes. TrueMass Sebum Panel analyses showed a reduction in saturated and monounsaturated fatty acyl chains across lipid species, including di- and triacylglycerols, phospholipids, cholesteryl esters, and wax esters in OG-treated sebocytes. There was no shift to shorter acyl chain lengths observed, suggesting that the fatty acid chain elongation process was not affected. OG is a pro-drug of the ACC inhibitor 5-(tetradecyloxy)-2-furoic acid and was designed to enhance delivery in vivo. Topical application of OG but not 5-(tetradecyloxy)-2-furoic acid significantly reduced hamster ear sebaceous gland size, indicating that this pro-drug approach was critical to obtain the desired activity in vivo. High-performance liquid chromatography analyses of hamster ear extracts showed that OG treatment increased ACC levels and the ratio of acetyl-CoA to free CoA in these animals, indicating increased fatty acid oxidation. These changes are consistent with ACC inhibition. Matrix-assisted laser desorption/ionization imaging showed that OG applied onto Yorkshire pig ears accumulated in sebaceous glands relative to the surrounding dermis. Sebaceous gland ACC represents an attractive therapeutic target given its central role in formation of sebum, a key factor in acne pathogenesis.

PMID:28259683 DOI:10.1016/j.jid.2016.12.031

J Am Acad Dermatol. 2017 Jan;76(1):33-39. doi: 10.1016/j.jaad.2016.08.053. Epub 2016 Oct 28.

Olumacostat glasaretil, a novel topical sebum inhibitor, in the treatment of acne vulgaris: A phase IIa, multicenter, randomized, vehicle-controlled study.

Bissonnette R[1], Poulin Y[2], Drew J[3], Hofland H[3], Tan J[4].

BACKGROUND: Olumacostat glasaretil (OG) inhibits acetyl-coenzyme A carboxylase, the enzyme responsible for the first, rate-limiting step in de novo fatty acid synthesis. OG inhibited in vitro human sebocyte lipid production and reduced in vivo sebaceous gland size in hamster ears.

OBJECTIVES: Safety and efficacy of OG 7.5% gel were evaluated in patients with moderate to severe facial acne vulgaris.

METHODS: Patients were randomized (1:1) to twice-daily application of OG or vehicle for 12 weeks. Efficacy was measured through changes in lesion counts and improvement in acne severity scores.

RESULTS: A total of 108 patients received OG (n = 53) or vehicle (n = 55); these groups had mean baseline counts of 29.7 and 28.6 inflammatory and 40.9 and 38.8 noninflammatory lesions, respectively. At week 12, OG treatment showed greater reductions from baseline in inflammatory lesions (-63.9% vs -45.9%; P = .0006) and noninflammatory lesions (-48.1% vs -28.8%; P = .0025), and more patients with greater than or equal to 2-grade improvement in investigator global assessment score (24.5% vs 7.3%; P = .0070) than vehicle. Application-site adverse events (typically mild or moderate intensity) were more common with OG.

LIMITATIONS: Larger trials are needed to optimize OG dosing and confirm the current results.

CONCLUSION: OG was well tolerated and showed evidence of efficacy, suggesting further development is warranted.

PMID:28029390 DOI:10.1016/j.jaad.2016.08.053

Cortexolone 17-alpha propionate

- promising peripherally selective antiandrogen
- cream 1% once daily bedtime x 8 weeks
- more effective on total and inflammatory lesions than placebo

Omiganan

- synthetic, antimicrobial peptide
- developed for prevention of catheter-related infections
- gel 0.1-2%
- antibacterial (Gram + or -), antifungal
- no results currently available in acne

Minocycline 1% and 4%

- foam galenic preparation
- RCT study – 4% once daily x 12 weeks
- moderate-to-severe acne
- greater reduction in I and NI in comparison with placebo
- higher rate of IGA score reduction

Curr Med Chem. 2017 Oct 9. doi: 10.2174/0929867324666171009120154. [Epub ahead of print]

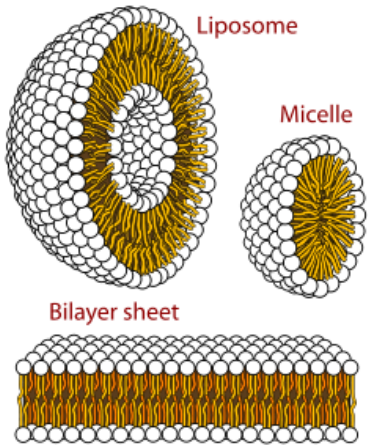
Recent advances and perspectives in liposomes for cutaneous drug delivery.

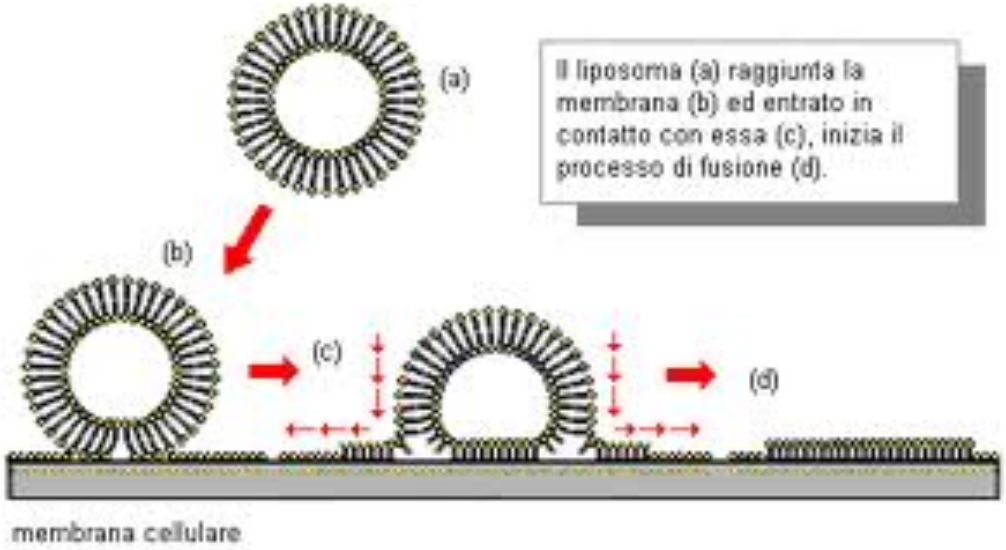
Caritá AC[1], Eloy JO[2], Chorilli M[2], Lee RJ[3], Leonardi GR[4].

The cutaneous route is attractive for the delivery of drugs in the treatment of a wide variety of diseases. However the stratum corneum (SC) is an effective barrier that hampers skin penetration. Within this context, liposomes emerge as a potential carrier for improving topical delivery of therapeutic agents. In this review, we aimed to discuss key aspects for the topical delivery by drug-loaded liposomes. Phospholipid type and phase transition temperature have been shown to affect liposomal topical delivery. The effect of surface charge is subject to considerable variation depending on drug and composition. In addition, modified vesicles with the presence of components for permeation enhancement, such as surfactants and solvents, have been shown to have a considerable effect. These liposomes include: Transfersomes, Niosomes, Ethosomes, Transethosomes, Invasomes, coated liposomes, penetration enhancer containing vesicles (PEVs), fatty acids vesicles, Archaeosomes and Marinosomes. Furthermore, adding polymeric coating onto liposome surface could influence cutaneous delivery. Mechanisms of delivery include intact vesicular skin penetration, free drug diffusion, permeation enhancement, vesicle adsorption to and/or fusion with the SC, trans-appendageal penetration, among others. Finally, several skin conditions, including acne, melasma, skin aging, fungal infections and skin cancer, have benefited from liposomal topical delivery of drugs, with promising in vitro and in vivo results. However, despite the existence of some clinical trials, more studies are needed to be conducted in order to explore the potential of liposomes in the dermatological field.

Liposomes

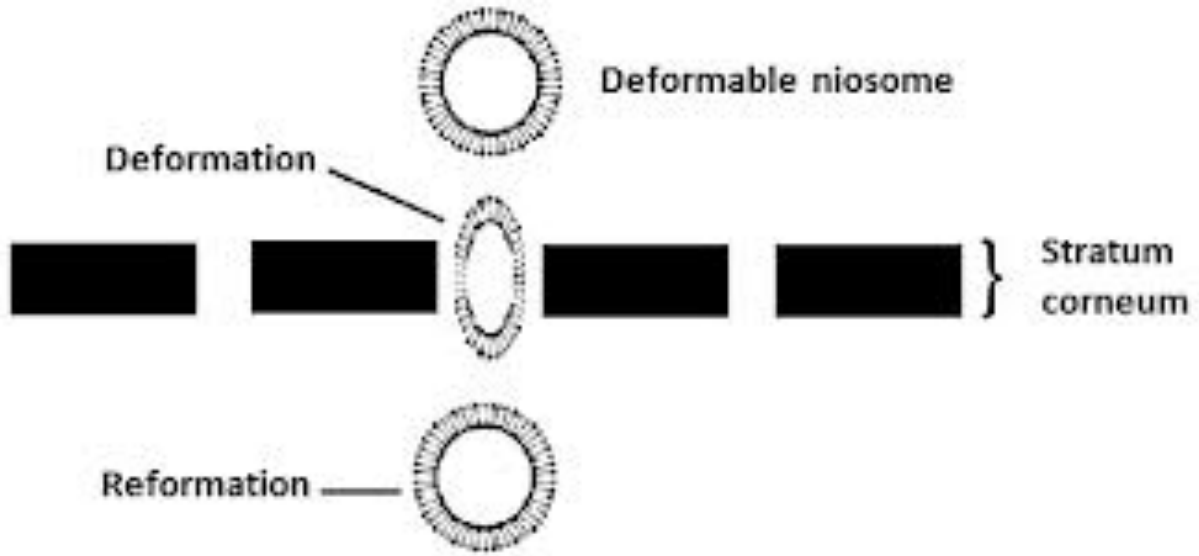
Definition	Spheric vesicles 50-500 nm Double layer of amphiphilic phospholipids with an aqueous core





Niosomes

Definition	Non ionic surfactant vesicles, less than 200 nm Evolution of liposomes
Advantages	Deformation



Polymer conjugated retinoids for controlled transdermal delivery

Steven A. Castleberry, Mohiuddin A. Quadir, Malak Abu Sharkh, Kevin E. Shopsowitz, Paula T. Hammond

ABSTRACT

All-trans retinoic acid (ATRA), a derivative of vitamin A, is a common component in cosmetics and commercial acne creams as well as being a first-line chemotherapeutic agent. Today, formulations for the topical application of ATRA rely on creams and emulsions to incorporate the highly hydrophobic ATRA drug. These strategies, when applied to the skin, deliver ATRA as a single bolus, which is immediately taken up into the skin and contributes to many of the known adverse side effects of ATRA treatment, including skin irritation and hair loss. Herein we present a new concept in topical delivery of retinoids by covalently bonding the drug through a hydrolytically degradable ester linkage to a common hydrophilic polymer, polyvinyl alcohol (PVA), creating an amphiphilic nanomaterial that is water-soluble. This PVA bound ATRA can then act as a pro-drug and accumulate within the skin to allow for the sustained controlled delivery of active ATRA. This approach was demonstrated to release active ATRA out to 10 days *in vitro* while significantly enhancing dermal accumulation of the ATRA in explant pig skin. *In vivo* we demonstrate that the pro-drug formulation reduces application site inflammation compared to free ATRA and retains the drug at the application site at measurable quantities for up to six days.

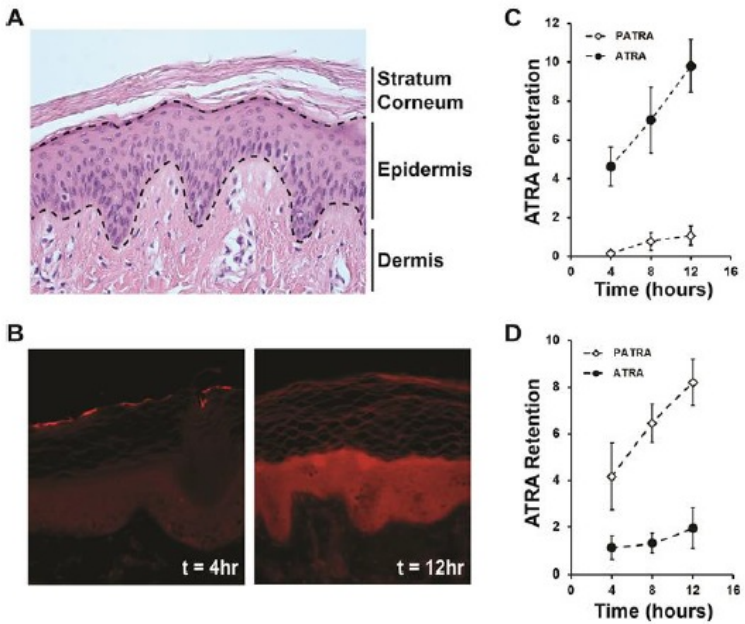


Fig. 6. Uptake and transport of ATRA in explant pig skin (a) Histological appearance of pig dermis. (b) Uptake of fluorescently labeled PATRA after 4 and 12 hours of exposure. Uptake is seen to significantly increase over this time and accumulate within the epidermis. (c) Fraction penetration of ATRA through pig dermis followed over 12 hours. (d) Quantification of fraction of ATRA accumulated within the pig dermis over 12 hours of exposure. Data shown is mean ± S.D., n=4.

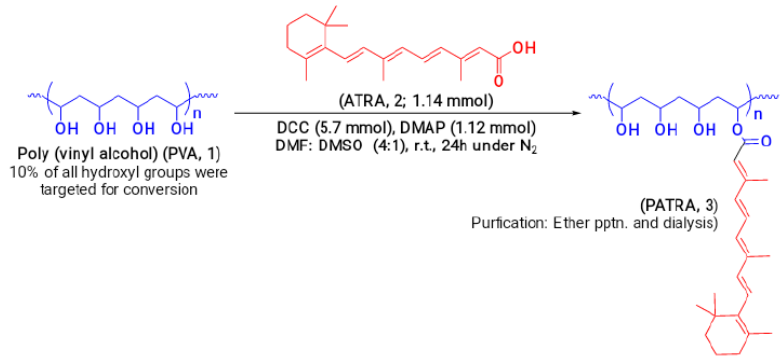


Fig.1. Chemical synthesis of PATRA (3): Conjugation of ATRA (2) to PVA (1) was performed using DCC chemistry in DMF:DMSO mixture for 24h at room temperature under nitrogen.

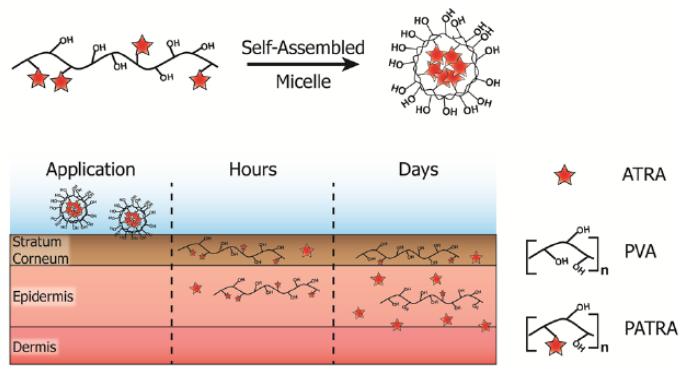


Fig. 2. Cartoon schematic of the adsorption of micellar PATRA into the dermis Release of ATRA from the PATRA conjugate occurs in the hydrated dermis.

Am J Clin Dermatol
DOI 10.1007/s40257-016-0178-4

ORIGINAL RESEARCH ARTICLE

Moderate and Severe Inflammatory Acne Vulgaris Effectively Treated with Single-Agent Therapy by a New Fixed-Dose Combination Adapalene 0.3 %/Benzoyl Peroxide 2.5 % Gel: A Randomized, Double-Blind, Parallel-Group, Controlled Study

Linda Stein Gold[1,6] · Jonathan Weiss[2] · Maria Jose Rueda[3] · Hong Liu[4] · Emil Tanghetti[5]

Abstract

Background A need exists for topical treatments in managing more severe inflammatory acne.

Objectives The objectives of this study were to evaluate the efficacy and safety of adapalene 0.3 %/benzoyl peroxide 2.5 % (0.3 % A/BPO) topical gel in subjects with moderate and severe inflammatory acne.

Methods This was a multicenter, randomized, double-blind, parallel-group study. Randomization was stratified by acne severity (50 % moderate and 50 % severe). Subjects received 0.3 % A/BPO, 0.1 % A/BPO (benchmark), or vehicle (comparator) once daily for 12 weeks. Co-primary efficacy endpoints were success rate at week 12 (the percentage of subjects rated 'clear' or 'almost clear' with at least a 2-grade improvement on Investigator's Global Assessment [IGA]) and change in inflammatory (IN) and noninflammatory (NIN) lesion counts from baseline to week 12. Secondary efficacy endpoints were percent changes in IN and NIN lesion counts. Safety endpoints were incidence of adverse events (AEs) and local tolerability signs/symptoms.

Results A total of 503 subjects were randomized: 217, 217, and 69 subjects in the 0.3 % A/BPO, 0.1 % A/BPO, and vehicle groups, respectively. For success rate (subjects rated 'clear' or 'almost clear' with ≥2-grade improvement in IGA), 0.3 % A/BPO was superior to vehicle, with a treatment difference of 22.7 % (33.7 vs. 11.0 %; 95 % confidence interval [CI] 12.8–32.6, $p < 0.001$). At week 12, 0.3 % A/BPO was superior to vehicle for mean reduction from baseline in IN (27.0 vs. 14.4) and NIN lesion counts (40.2 vs. 18.5), as well as for percentage reduction from baseline in IN (68.7 vs. 39.2 %) and NIN lesion counts (68.3 vs. 37.4 %) (all $p < 0.001$). Among subjects with severe inflammatory acne (IGA = 4), 0.1 % A/BPO did not reach statistical significance for success rate compared with vehicle ($p = 0.443$), whereas 0.3 % A/BPO demonstrated significantly greater efficacy ($p = 0.029$, requiring ≥3-point IGA improvement). Additionally, 0.3 % A/BPO was safe and well-tolerated.

Conclusions Results of this clinical trial demonstrate the significantly greater efficacy of adapalene 0.3 % A/BPO topical gel compared with vehicle as well as a good safety profile in the treatment of moderate to severe inflammatory non-nodulocystic acne, which increases patients' treatment options.

Clinicaltrials.gov identifier NCT01880320.

Am J Clin Dermatol
DOI 10.1007/s40257-016-0178-4

ORIGINAL RESEARCH ARTICLE

Moderate and Severe Inflammatory Acne Vulgaris Effectively Treated with Single-Agent Therapy by a New Fixed-Dose Combination Adapalene 0.3 %/Benzoyl Peroxide 2.5 % Gel: A Randomized, Double-Blind, Parallel-Group, Controlled Study

Linda Stein Gold[1,6] · Jonathan Weiss[2] · Maria Jose Rueda[3] · Hong Liu[4] · Emil Tanghetti[5]

Table 2 Co-primary efficacy endpoint: success rate[a] (% IGA clear/almost clear, ITT)

	Success rate	
	0.3 % A/BPO	Vehicle
Week 1	1	0
Week 2	3.0	0
Week 4	4.3	1.5
Week 8	13*	3.1
Week 12	33.7**	11

A adapalene, *BPO* benzoyl peroxide, *IGA* Investigator's Global Assessment, *ITT* intent to treat population

* $p < 0.05$ vs. vehicle

** $p < 0.001$ vs. vehicle

[a] Multiple imputation data; post hoc analysis performed prior to week 12

Fig. 5 Mean percent change (MI data; post hoc analysis performed prior to week 12) in (**a**) inflammatory lesions and (**b**) non-inflammatory lesions (ITT; MI). *A* adapalene, *BPO* benzoyl peroxide, *ITT* intent to treat, *MI* multiple imputation. *$p < 0.05$, **$p < 0.001$

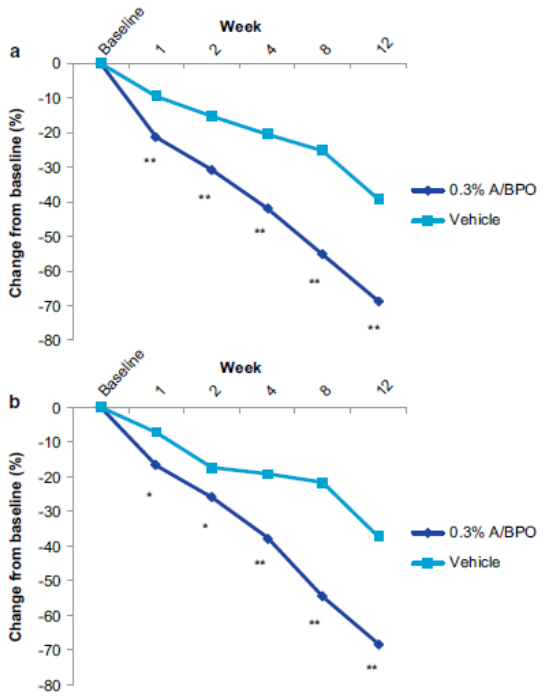
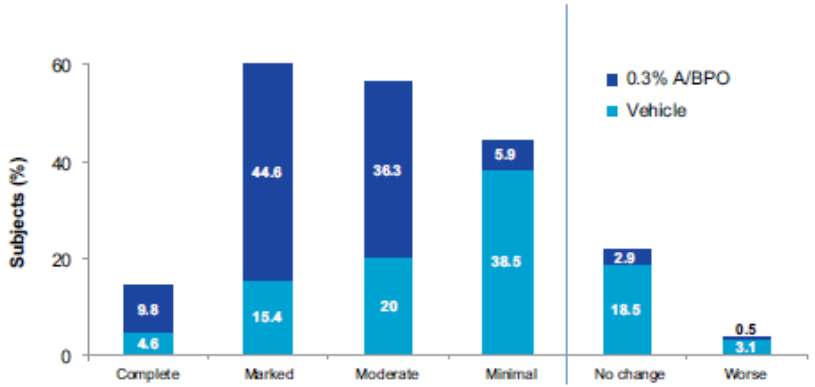


Fig. 7 Subject's assessment of acne improvement (week 12, intent-to-treat population). *A* adapalene, *BPO* benzoyl peroxide



Ann Dermatol Venereol. 2017 Oct 6. pii: S0151-9638(17)30322-8. doi: 10.1016/j.annder.2017.08.011. [Epub ahead of print]

[Cosmetics and topical medications in acne: Where is the boundary?]

Poli F[1], Claudel JP[2], Auffret N[3], Leccia MT[4], Dréno B[5].

Acne is a chronic disease that may cause sequels such as atrophic or hypertrophic scars or post-inflammatory hyperpigmentation. Topicaland systemic medications with proven pharmacologic activity and which have received marketing authorization are the key actors in the treatment of acne. However, these topical or systemic treatments frequently cause adverse effects related to impairment of the skin barrier, and cosmetics must therefore be used in combination to help protect the skin barrier. Nowadays, new cosmetic products containing active ingredients tested in vitro or in a small number of subjects have changed the world of cosmetics. In being described as "dermo-cosmetic" and in integrating active ingredients in their formulations, these cosmetics are now being presented as being specifically adapted for a given disease, and no longer limited to skin care and hygiene but suitable as an adjunctive or even an alternative to current medications. The aim of this article is to provide a better understanding of the respective roles of medications and cosmetics in the management of acne.

Conclusions:

- Vehicles

- Non pharmacologically active substances

- Topical products for moderate / severe acne

- Maintenance treatment (topical retinoid +/- BPO)

- Incoming products

- Personalized treatment

European Evidence-based (S3)

Guideline for the Treatment of Acne

(ICD L70.0)

Update 2016

Long version

Expiry date: 31.12.2020

A. Nast[1], B. Dréno[2], V. Bettoli[3], Z. Bukvic Mokos[4], K. Degitz[5], C. Dressler[1], A.Y. Finlay[6], M. Haedersdal[7], J. Lambert[8], A. Layton[9], H.B. Lomholt[10], J.L. López-Estebaranz[11], F. Ochsendorf[12], C. Oprica[13], S. Rosumeck[1], T. Simonart[14], R.N. Werner[1], H. Gollnick[15]

www.edf.com

Short version: JEADV 2016

5 Induction therapy

Summary of therapeutic recommendations [1] for induction therapy

Recommendations are based on available evidence and expert consensus. Available evidence and expert voting lead to classification of strength of recommendation.

	Comedonal acne [3]	Mild to moderate papulopustular acne	Severe papulopustular/ moderate nodular acne	Severe nodular/ conglobate acne [13]
High strength of recommen-dation	-	Adapalene + BPO (f.c.) *or* BPO + Clindamycin (f.c.) [5]	Isotretinoin	Isotretinoin
Medium strength of recommen-dation	Topical retinoid [4]	Azelaic acid *or* BPO *or* Topical Retinoid [4] *or* Topical Clindamycin + Tretinoin (f.c.) [5,6] *or* Systemic Antibiotic [5,7,8] + Adapalene [9]	Systemic Antibiotic [5,8] + Adapalene [9] *or* Systemic Antibiotic [5,8] + Azelaic acid [10] or Systemic Antibiotic [5,8] + Adapalene + BPO (f.c.)	Systemic Antibiotic [5,8] + Azelaic Acid or Systemic Antibiotic [5,8] + Adapalene + BPO (f.c.)
Low strength of recommen-dation	Azelaic acid *or* BPO	Blue Light *or* Oral Zinc *or* Systemic Antibiotic [5,7,8] + Azelaic Acid [10] *or* Systemic Antibiotic [5,7,8] + Adapalene + BPO (f.c.) [11] *or* Systemic Antibiotic [5,7,8] + BPO [12] *or* Topical Erythromycin + Isotretinoin (f.c.) [5] *or* Topical Erythromycin + Tretinoin (f.c.) [5]	Systemic Antibiotic [5,8] + BPO [12]	Systemic Antibiotic [5,8] + Adapalene [9,11] *or* Systemic Antibiotics [5,8] + BPO [11]
Alternatives for females [2]	-	-	Hormonal Antiandrogens + Systemic Antibiotic [5,8] + Topicals (apart from antibiotics) *or* Hormonal Antiandrogens + Topical Treatment (apart from antibiotics)	Hormonal Antiandrogens + Systemic Antibiotic [5,8] + Topicals (apart from antibiotics) *or* Hormonal Antiandrogens + Topical Treatment (apart from antibiotics)

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Guidelines of care for the management of acne vulgaris

Work Group: Andrea L. Zaenglein, MD (Co-Chair),[a] Arun L. Pathy, MD (Co-Chair),[b] Bethanee J. Schlosser, MD, PhD,[c] Ali Alikhan, MD,[d] Hilary E. Baldwin, MD,[e] Diane S. Berson, MD,[f,g] Whitney P. Bowe, MD,[e] Emmy M. Graber, MD,[h,i] Julie C. Harper, MD,[j] Sewon Kang, MD,[k] Jonette E. Keri, MD, PhD,[l,m] James J. Leyden, MD,[n] Rachel V. Reynolds, MD,[o,p] Nanette B. Silverberg, MD,[q,r] Linda F. Stein Gold, MD,[s] Megha M. Tollefson, MD,[t] Jonathan S. Weiss, MD,[u] Nancy C. Dolan, MD,[c] Andrew A. Sagan, MD,[v] Mackenzie Stern,[c] Kevin M. Boyer, MPH,[w] and Reva Bhushan, MA, PhD[w]

Hershey and Philadelphia, Pennsylvania; Centennial, Colorado; Chicago and Schaumburg, Illinois; Cincinnati, Ohio; New York, New York; Boston, Massachusetts; Birmingham, Alabama; Baltimore, Maryland; Miami, Florida; Detroit, Michigan; Rochester, Minnesota; and Atlanta, Georgia

Acne is one of the most common disorders treated by dermatologists and other health care providers. While it most often affects adolescents, it is not uncommon in adults and can also be seen in children. This evidence-based guideline addresses important clinical questions that arise in its management. Issues from grading of acne to the topical and systemic management of the disease are reviewed. Suggestions on use are provided based on available evidence. (J Am Acad Dermatol http://dx.doi.org/10.1016/j.jaad.2015.12.037.)

	Mild	Moderate	Severe
1st Line Treatment	Benzoyl Peroxide (BP) or Topical Retinoid -or- Topical Combination Therapy** BP + Antibiotic or Retinoid + BP or Retinoid + BP + Antibiotic	Topical Combination Therapy** BP + Antibiotic or Retinoid + BP or Retinoid + BP + Antibiotic -or- Oral Antibiotic + Topical Retinoid + BP -or- Oral Antibiotic + Topical Retinoid + BP + Topical Antibiotic	Oral Antibiotic + Topical Combination Therapy** BP + Antibiotic or Retinoid + BP or Retinoid + BP + Antibiotic -or- Oral Isotretinoin
Alternative Treatment	Add Topical Retinoid or BP (if not on already) -or- Consider Alternate Retinoid -or- Consider Topical Dapsone	Consider Alternate Combination Therapy -or- Consider Change in Oral Antibiotic -or- Add Combined Oral Contraceptive or Oral Spironolactone (Females) -or- Consider Oral Isotretinoin	Consider Change in Oral Antibiotic -or- Add Combined Oral Contraceptive or Oral Spironolactone (Females) -or- Consider Oral Isotretinoin

Fig 1. Treatment algorithm for the management of acne vulgaris in adolescents and young adults. The *double asterisks* (**) indicate that the drug may be prescribed as a fixed combination product or as separate component. *BP,* Benzoyl peroxide.

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